

CLAIMS

1. A methylphenidate solution comprising:
methylphenidate; and
at least one pharmaceutically acceptable organic acid, wherein the methylphenidate and the at least one organic acid are dissolved in a solvent system and the solvent system comprising at least one non-aqueous solvent.
2. The methylphenidate solution according to claim 1, wherein the at least one organic acid is present in the methylphenidate solution from about 0.5 mg/ml to about 5.0 mg/ml.
3. The methylphenidate solution according to claim 1, wherein the solvent system further comprises water.
4. The methylphenidate solution according to claim 3, wherein the water is up to 50% of the solvent system.
5. The methylphenidate solution according to claim 1, wherein the at least one non-aqueous solvent is from about 50% to about 100% of the solvent system.
6. The methylphenidate solution according to claim 1, wherein the at least one organic acid is selected from the group consisting of acetic acid, ascorbic acid, citric acid, fumaric acid, malic acid, succinic acid, tartaric acid and mixtures thereof.
7. The methylphenidate solution according to claim 1, wherein the at least one non-aqueous solvent is selected from the group consisting of polyols, glycols and mixtures thereof.

8. The methylphenidate solution according to claim 1, further including at least one pharmaceutical additive selected from the group consisting of flavorings, colorants, buffers, preservatives and mixtures thereof.

9. A methylphenidate HCl solution comprising:

about 0.1 mg/ml to about 10.0 mg/ml methylphenidate HCl; and

about 0.5 mg/ml to about 5.0 mg/ml of at least one organic acid, the methylphenidate HCl and the at least one organic acid being dissolved in a solvent system, the solvent system comprising:

up to about 50% water;

about 30% to about 70% of at least one polyol solvent; and

about 10% to about 70% of at least one glycol solvent.

10. The methylphenidate HCl solution according to claim 9, wherein the at least one organic acid is selected from the group consisting of acetic acid, ascorbic acid, citric acid, fumaric acid, malic acid, succinic acid, tartaric acid and mixtures thereof.

11. The methylphenidate HCl solution according to claim 9, wherein the at least one polyol solvent is selected from the group consisting of glycerin, sorbitol, sucrose, fructose and mixtures thereof.

12. The methylphenidate HCl solution according to claim 9, wherein the at least one glycol solvent is selected from the group consisting of propylene glycol, polyalkylene glycol products and mixtures thereof.

13. The methylphenidate HCl solution according to claim 9, further including at least one pharmaceutical additive selected from the group consisting of flavorings, colorants, buffers, preservatives and mixtures thereof.

14. A methylphenidate HCl solution comprising:

about 0.1 mg/ml to about 10.0 mg/ml methylphenidate HCl; and
about 0.5 mg/ml to about 3.0 mg/ml of at least one organic acid, the
methylphenidate HCl and the at least one organic acid being dissolved in a solvent
system, the solvent system comprising:

about 10% to about 45% water;
about 40% to about 60% of at least one polyol solvent; and
about 10% to about 30% of at least one glycol solvent.

15. The methylphenidate HCl solution according to claim 14, wherein the at least
one organic acid is selected from the group consisting of acetic acid, ascorbic acid, citric
acid, fumaric acid, malic acid, succinic acid, tartaric acid and mixtures thereof.

16. The methylphenidate HCl solution according to claim 14, wherein the at least
one polyol solvent is selected from the group consisting of glycerin, sorbitol, sucrose,
fructose and mixtures thereof.

17. The methylphenidate HCl solution according to claim 14, wherein the at least
one glycol solvent is selected from the group consisting of propylene glycol, polyalkylene
glycol products and mixtures thereof.

18. The methylphenidate HCl solution according to claim 14, further including at
least one pharmaceutical additive selected from the group consisting of flavorings,
colorants, buffers, preservatives and mixtures thereof.

19. A methylphenidate HCl solution comprising:

about 0.1 mg/ml to about 10.0 mg/ml methylphenidate HCl; and
about 0.5 mg/ml to about 1.5 mg/ml of at least one organic acid, the
methylphenidate HCl and the at least one organic acid being dissolved in a solvent
system, the solvent system comprising:

about 30% to about 40% water;

about 45% to about 55% of at least one polyol solvent; and
about 10% to about 20% of at least one glycol solvent.

20. The methylphenidate HCl solution according to claim 19, wherein the at least one organic acid includes citric acid.

21. The methylphenidate HCl solution according to claim 19, wherein the at least one polyol solvent includes glycerin.

22. The methylphenidate HCl solution according to claim 19, wherein the at least one glycol solvent includes polyethylene glycol.

23. The methylphenidate HCl solution according to claim 19, further including at least one pharmaceutical additive selected from the group consisting of flavorings, colorants, buffer, preservatives and mixtures thereof.

24. A method of treating a patient for a disorder treatable by methylphenidate which comprises administering a therapeutically effective amount of methylphenidate in a liquid solution.

25. The method of treating a patient for a disorder treatable by methylphenidate of claim 24, the methylphenidate solution comprising:

methylphenidate and at least one organic acid in a solvent system, wherein the solvent system includes at least one non-aqueous solvent.

26. The method of treating a patient for a disorder treatable by methylphenidate according to claim 24, wherein the administering of the methylphenidate in a liquid solution is selected from the group consisting of oral administration, intravenous administration and inhalation administration.

27. The method of treating a patient for a disorder treatable by methylphenidate according to claim 24, which further includes storing the methylphenidate solution in a non-reactive container for a predetermined period of time prior to administering the methylphenidate solution.

28. The method of treating a patient for a disorder treatable by methylphenidate according to claim 25, wherein the at least one organic acid is present in the methylphenidate solution from about 0.5 mg/ml to about 5.0 mg/ml.

29. The method of treating a patient for a disorder treatable by methylphenidate according to claim 25, wherein the solvent system further includes water.

30. The method of treating a patient for a disorder treatable by methylphenidate according to claim 25, wherein the water is up to 50% of the solvent solution.

31. The method of treating a patient for a disorder treatable by methylphenidate according to claim 25, wherein the at least one non-aqueous solvent is from about 50% to about 100% of solvent solution.

32. The method of treating a patient for a disorder treatable by methylphenidate according to claim 25, wherein the at least one organic acid is selected from the group consisting of acetic acid, ascorbic acid, citric acid, fumaric acid, malic acid, succinic acid, tartaric acid and mixtures thereof.

33. The method of treating a patient for a disorder treatable by methylphenidate according to claim 25, wherein the at least one non-aqueous solvent is selected from the group consisting of polyols, glycols and mixtures thereof.

34. The method of treating a patient for a disorder treatable by methylphenidate according to claim 25, which further includes dissolving at least one pharmaceutical

additive selected from the group consisting of flavorings, colorants, buffers, preservatives and mixtures thereof into the methylphenidate solution.

35. A method of producing a chemically stable methylphenidate solution comprising:

determining a dosage of methylphenidate;

dissolving the methylphenidate and about 0.5mg/ml to about 5.0 mg/ml of at least one organic acid in a solvent system, the solvent system comprising:

up to about 50% water;

about 30% to about 70% of at least one polyol solvent; and

about 10% to about 70% of at least one glycol solvent.

36. The method for producing a methylphenidate solution according to claim 35, wherein the at least one organic acid is selected from the group consisting of acetic acid, ascorbic acid, citric acid, fumaric acid, malic acid, succinic acid, tartaric acid and mixtures thereof.

37. The method for producing a methylphenidate solution according to claim 35, wherein the at least one polyol solvent is selected from the group consisting of glycerin, sorbitol, sucrose, fructose and mixtures thereof.

38. The method for producing a methylphenidate solution according to claim 35, wherein the at least one glycol solvent is selected from the group consisting of propylene glycol, polyalkylene glycol products and mixtures thereof.

39. The method for producing a methylphenidate solution according to claim 35, further including dissolving at least one pharmaceutical additive selected from the group consisting of flavorings, colorants, buffers, preservatives and mixtures thereof into the methylphenidate solution.

40. A method of producing a methylphenidate HCl solution comprising:
determining a dosage of methylphenidate HCl;
dissolving the of methylphenidate HCl and about 0.5mg/ml to about 5.0 mg/ml of
at least one organic acid in a solvent system, the solvent system comprising:
about 10% to about 45% water;
about 40% to about 60% of at least one polyol solvent; and
about 10% to about 30% of at least one glycol solvent.

41. The method for producing a methylphenidate HCl solution according to claim 40, wherein the at least one organic acid is selected from the group consisting of acetic acid, ascorbic acid, citric acid, fumaric acid, malic acid, succinic acid, tartaric acid and mixtures thereof.

42. The method for producing a methylphenidate HCl solution according to claim 40, wherein the at least one polyol solvent is selected from the group consisting of glycerin, sorbitol, sucrose, fructose and mixtures thereof.

43. The method for producing a methylphenidate HCl solution according to claim 40, wherein the at least one glycol solvent is selected from the group consisting of propylene glycol, polyalkylene glycol products and mixtures thereof.

44. The method for producing a methylphenidate HCl solution according to claim 40, further including dissolving at least one pharmaceutical additive selected from the group consisting of flavorings, colorants, buffers, preservatives and mixtures thereof into the methylphenidate HCl solution.

45. A method of producing a methylphenidate HCl solution comprising;
determining a dosage of methylphenidate HCl from about 0.1 mg/ml to about 10 mg/ml;

dissolving the of methylphenidate HCL and about 0.5mg/ml to about 1.5 mg/ml of at least one organic acid in a solvent system, the solvent system comprising:

about 30% to about 40% water;
about 45% to about 55% of at least one polyol solvent; and
about 10% to about 20% of at least one glycol solvent.

46. The method for producing a methylphenidate HCl solution according to claim 45, wherein the at least one organic acid is selected from the group consisting of acetic acid, ascorbic acid, citric acid, fumaric acid, malic acid, succinic acid, tartaric acid and mixtures thereof.

47. The method for producing a methylphenidate HCl solution according to claim 45, wherein the at least one polyol solvent is selected from the group consisting of glycerin, sorbitol, sucrose, fructose and mixtures thereof.

48. The method for producing a methylphenidate HCl solution according to claim 45, wherein the wherein the at least one glycol solvent is selected from the group consisting of propylene glycol, polyalkylene glycol products and mixtures thereof.

49. The method for producing a methylphenidate HCl solution according to claim 45, further including dissolving at least one pharmaceutical additive selected from the group consisting of flavorings, colorants, buffers, preservatives and mixtures thereof into the methylphenidate solution.